A summary of 510(k) safety and effectiveness information in accordance with the requirements of 21 CFR 807.92.

Submitter Information	
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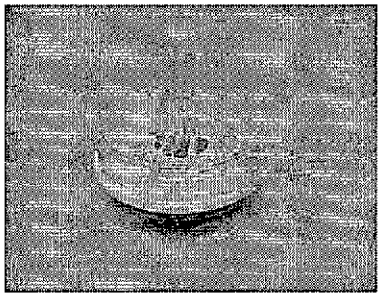
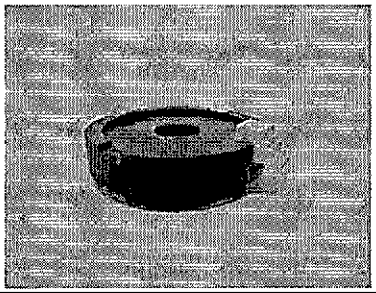
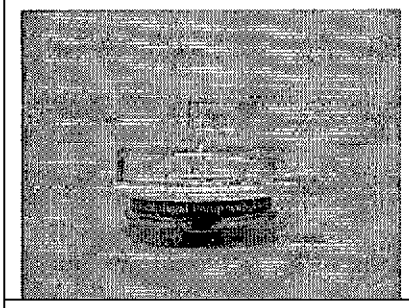
Establishment Registration Number	1828100
Name of contact person	Rebecca Andersen
Submission Co-Authors	Kevin Kong, RAC and Rebecca Andersen, PhD
Date prepared	7/29/2011
Name of Device	
Trade or proprietary name	Sarns® Centrifugal Pump (With or without X-Coating™)
Common or usual name	Centrifugal Pump
Classification name	Nonroller-type cardiopulmonary bypass blood pump
Classification panel	74 Cardiovascular
Regulation	21 CFR § 870.4360
Product Code(s)	KFM
Legally marketed device(s) to which equivalence is claimed	Sarns® Centrifugal Pump (With or without X-Coating™) (K020998 & K915363)

TERUMO

Reason for 510(k) submission	This application seeks clearance for updates to the device and to expand the indications for use. This application includes the reusable Sarns® Centrifugal Pump Adapter which facilitates use of the sterile disposable Sarns® Centrifugal pump with Stöckert Centrifugal Pump Systems.
Device description  	The Sarns® Centrifugal Pump (with or without X-Coating™) is a single use, sterile and disposable device. It is used to pump blood through the extracorporeal circuit during cardiopulmonary bypass surgery and may be used for up to 6 hours. The pump has a priming volume of 48ml. The pump rotational speed is 0-3600 RPM resulting in a flow capacity of 0-9.9 LPM. With this submission, the sterile disposable Sarns® Centrifugal pump may be used with Stöckert Centrifugal pump systems when the reusable Sarns® Centrifugal Pump Adapter is used. The Sarns® Centrifugal Pump Adapter is a device designed with geometries that mate the Stöckert centrifugal systems to the Sarns® Centrifugal pump. The housing is a hard plastic (acetal) that slides easily onto the Sarns® Centrifugal pump then clips into place. The adapted pump is then mounted onto the Stöckert Centrifugal pump systems.
Indications for use 	The Sarns® Centrifugal Pump (with or without X-Coating™) is a sterile, single use device, used as an extracorporeal blood pump for use in cardiopulmonary bypass procedures for up to 6 hours. The pump is intended for use with the Sarns® Centrifugal Systems or may be used with Stöckert Centrifugal Pump Systems by attaching the Sarns® Centrifugal Pump Adapter.
Intended use	The pump is intended for use with the Sarns® Centrifugal Systems or may be used with Stöckert Centrifugal pump systems by attaching the Sarns® Centrifugal Pump Adapter.

PERFORMANCE DATA

Summary of the technological characteristics of the device compared to the predicate device

Characteristic	Proposed Device: Sarns® Centrifugal Pump with or without X-Coating™ and reusable Sarns® Centrifugal Pump Adapter	Predicate: Sarns® Centrifugal Pump with(K020998) or without (K915363) X-Coating™
Pump functionality	Propels blood through the extracorporeal circuit via centrifugal force created by an impeller.	Same
Pump Material: Housing	Polycarbonate (adapter housing is acetal)	Same
Pump Design	A polycarbonate case housing a magnetically driven acrylic vaned impeller which spins to create centrifugal force. This propels blood through the extracorporeal circuit.	Same
Pump Operating Principle/Technology	Movement of blood through the extracorporeal circuit via centrifugal force created by an impeller. The blood flows in to a pump chamber at the inlet port. It is moved by the impeller to the outlet port.	Same
Pump Prime Volume	48 mL	Same
Pump Motor Interface	Magnetic Coupling (Adapter also couples magnetically)	Same
Pump Inlet/Outlet Port Diameters	3/8 inch (9.5mm)	Same
Pump Sterilization	Ethylene Oxide (Adapter is non-sterile)	Same
Pump SAL	10^{-6} (Adapter is non-sterile)	Same
Magnet	Ceramic Iron Ferrite (Adapter is NdFeB with Ni plating)	Ceramic Iron Ferrite

SUMMARY OF NON-CLINICAL TESTS CONDUCTED FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE*		
Performance Test Summary-Proposed Device		
Characteristic	**Standard/Test/FDA Guidance**	**Results Summary**
Flow curves: A test that demonstrates the performance of the sterile disposable pump has not changed when used with the reusable Sarns® Centrifugal Pump adapter on the Stöckert Centrifugal Pump System	Flow Curves Performance Test	**PASS:** Back pressure ranges for the proposed device configuration are within range of the predicate device configuration
Reusable Sarns® Centrifugal Pump Adapter clip fatigue test: Shows the clipping mechanism is rated for the lifetime use of 7yrs	Reusable Centrifugal pump adapter clip fatigue Test	**PASS:** The reusable adapter has passed test meeting the lifetime use of 7 years
Reusable Sarns® Centrifugal Pump Adapter change out time test: To show that the change out time of the pump on the proposed device configuration is similar to the pump change out time of the predicate device configuration:	Reusable Centrifugal pump adapter change out time test	**PASS:** The change out time between the predicate device configuration and the proposed device configuration showed no statistical difference
Shipping and Durability test: Show that the Sarns® Centrifugal Pump Adapter show no signs of damage after shipment and functions as intended after shipment	Shipping and Durability Test	**PASS:** Sarns® Centrifugal Pump Adapter showed no signs of damage and functioned as intended following testing

Characteristic	**Standard/Test/FDA Guidance**	**Results Summary**
Hemolysis test: To show that is there is no statistical difference of the effect on plasma free hemoglobin, white blood cell count and platelet count between the sterile disposable Sarns® Centrifugal Pump with reusable adapter and without reusable adapter	Hemolysis testing for the reusable Sarns® Centrifugal Adapter	**Pass:** No adverse statistical differences found between plasma free hemoglobin, white blood cell count and platelet count while using the sterile disposable Sarns® Centrifugal Pump with or without adapter
Reusable Sarns® Centrifugal Pump Adapter disconnection force: To show that the force necessary to disconnect the sterile disposable Sarns® Centrifugal Pump with or without X-Coating™ from the reusable Sarns® Centrifugal Pump Adapter is similar or stronger to disconnecting the pump from the predicate device configuration	Centrifugal adapter disconnection force	**PASS:** The average disconnection force required to separate the Sarns® Centrifugal Pump from the reusable Sarns® Centrifugal Pump Adapter was greater than the force required to separate the predicate Sarns® Centrifugal Pump
Reusable Sarns® Centrifugal Adapter, Interaction with the Sorin Heart Lung Machine: To show that usage of the reusable Sarns® Centrifugal Pump Adapter does not interfere with the control and safety components of the Stöckert system	Centrifugal Adapter Interaction with a Heart Lung Machine	**PASS:** Usage of the reusable Sarns® Centrifugal Pump Adapter did not interfere with control and safety components of the Stöckert system

Summary of Non clinical tests conducted for determination of substantial equivalence
The Sarns® Centrifugal Pumps passed all the testing criteria and are shown to have the same level of performance when used with the adapter on Stöckert Centrifugal Pump Systems. Therefore the devices used with the adapter on a Stöckert Centrifugal Pump System are substantially equivalent to the devices when used on Sarns® Centrifugal Pump systems.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

DEC - 9 2011

Terumo Cardiovascular Systems
c/o Rebecca Andersen, Ph.D.
Director, Global Regulatory Affairs
6200 Jackson Road
Ann Arbor, MI 48103

Re: K112229
Sarn Centrifugal Pump
Regulation Number: 21 CFR 870.4360
Regulation Name: Pump, Blood, Cardiopulmonary Bypass, Non-Roller Type
Regulatory Class: Class III (three)
Product Code: KFM
Dated: December 2, 2011
Received: December 5, 2011

Dear Dr. Andersen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

M. G. Hillebrenner

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): **K112229**

Device Name: **Sarns® Centrifugal Pump with or without adapter**

Indications for Use:
The Sarns® Centrifugal Pump with or without X-Coating™ is a sterile, single use device, used as an extracorporeal blood pump for use in cardiopulmonary bypass procedures for up to 6 hours.

The pump is intended for use with the Sarns® Centrifugal Systems or may be used with Stöckert Centrifugal Pump Systems by attaching the Sarns® Centrifugal Pump Adapter.

Prescription Use _X___ AND/OR Over-The-Counter Use ___
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

M A Hillebrenner

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K112229